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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/490,965	01/24/2000	Michael J Heller	249/292	7864

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O'MELVENY & MEYERS  
114 PACIFICA, SUITE 100  
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EXAMINER

MARSCHEL, ARDIN H

ART UNIT	PAPER NUMBER
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1631

10

DATE MAILED: 12/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Applicati n N .

09/490,965

Applicant(s)

HELLER ET AL.

Examiner

Ardin Marschel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 83-91 and 95-107 is/are pending in the application.  
~~Claim(s) 1-82 and 92-94 have been canceled. (Not withdrawn from consideration).~~
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 83-91 and 95-107 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ 6) ☒ Other: Attachment for PTO-948.

**DETAILED ACTION**  
**WITHDRAWAL OF SUSPENSION**

Upon reconsideration, the two previously reviewed and possibly interfering U.S. Patents are deemed to be lacking in support regarding interfering subject matter. The first Patent considered is that of Shieh (P/N 6,030,781). The claimed subject matter of Shieh requires for all embodiments the analysis of markers which have been covalently bonded to a plurality of oligonucleotide segments which are present as a result of oligonucleotide ligase bonding methodology. No such marker practice combined with ligase bonding and analysis is present in the instant claims. The second Patent considered is that of Montgomery (P/N 6,093,302). The following limitations are present in the independent claims of Montgomery which are not present in the instant claims. There is a limitation to require the presence of a buffering or scavenging solution in contact with an electrode to prevent electrochemically generated reagents from leaving the locality of the electrode in independent claims 1 and 45 of Montgomery. There is a limitation to require repetitive synthesis of at least two separate polymers of desired length on the substrate surface thus making an array of such polymers in independent claims 15 and 40. This reconsideration has resulted in a withdrawal of the suspension for interference regarding the instant application.

However, also, upon reconsideration, the following rejections and/or objections are newly applied. They constitute the complete set presently being applied to the instant application.

### **DRAWING INFORMALITIES**

Applicants are hereby notified that the required timing for the correction of drawings has changed. See the last 6 lines on the sheet which is attached entitled "Attachment for PTO-948 (Rev. 03/01 or earlier)". It is noted that a PTO Form 948 was mailed with Paper No. 3 on 12/12/00. Due to the above notification, applicants are required to submit drawing corrections within the time period set for responding to this Office action. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this Office action.

### **TITLE**

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The present title is directed to stringency control methods whereas, in contrast, the presently pending claims lack any such stringency limitations.

### **VAGUENESS AND INDEFINITENESS**

Claims 83-91 and 95-107 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 83 cites the providing of "an electronically addressable location" in line 3. This causes the metes and bounds of the claim to be vague and indefinite. Several alternatives as to what is meant thereby. One interpretation is the simply practice of applying an electronic signal to the location which is thus addressed as to whatever electrical connection(s) is required. Another interpretation is that a surface is meant

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with multiple locations which are separately addressable or electronically selectable, such an array of such locations as also shown in Figure 3, labeled as a self-addressable chip. The presence of Figure 3 and related description may imply such an interpretation. It, however, is noted that the addressability in the instant claims is not worded as being "self-addressable", nor is there are array or multiple location limitation in the instant claims. The first simplistic addressability interpretation seems to be what is meant by the broad wording of the claims without any specifics directed to the second interpretation. If applicants intended that array type location layout practice is meant for the electronic addressability limitations in the instant claims, this is not clear from the claim wording. It is noted that implied limitations fail to be clear and concise as required for claim limitations under 35 U.S.C. § 112, second paragraph. This unclarity is also present in claim 91 as well as in claims which depend directly or indirectly from claims 83 or 91, due to their dependence. Clarification via clearer claim wording is requested.

### **PRIOR ART**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 83, 84, and 96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kreisher (P/N 4,589,965), taken in view of Ramachandran et al. (P/N 5,109,124).

Kreisher describes the practice of electroblotting which utilizes an electrode on one side of a gel with a membrane/paper and electrode on the other side to transfer proteins, nucleic acids, and other materials to the paper or membrane in column 1, lines 31-57. Opposite charge to whatever material or molecule is being transferred is required for such electroblotting to be operative as is instantly claimed also. This general process binds the transferred molecules to the membrane as described in the bridging sentence between columns 1 and 2. The SUMMARY OF THE INVENTION section in columns 2-3 describes the invention as improving on electroblotting using plate electrodes. Various additional materials which may be electroblotted in this manner are described in column 3, lines 28-67. Of specific interest is the generic suggestion and motivation in column 3, lines 28-67, for utilizing a variety of biochemical reaction types and materials including hybridization probes, various labeling methods, double reactions (line 61) to identify probes, and substrate/enzyme reactions on the blot (lines 65-67). This column 3 section; as well as column 3, line 68, through column 4, line 4; is reasonably directed to suggesting and motivating the practice of a variety of biochemical reactions on blotted, solid support bound, materials and/or molecules. Kreisher does not specify particular reactions such as where a substrate is bound via the electroblotting followed by enzyme reaction as in instant claim 83 or the PCR type

amplification reaction as in instant claim 91. It is also noted that the above rejection under 35 U.S.C. § 112, second paragraph, sets forth claim wording interpretation which documents that the electronically addressed electrode(s) of Kreisher is a reasonable interpretation of the instant claims regarding the electronically addressable location with an electrode as in the instant claims.

Ramachandran et al. describes the detection of a polynucleotide probe via signalling moieties as summarized in the abstract. Such a probe is utilized to hybridize to a target nucleic acid as further described in column 5, lines 38-52. This is exemplified in more detail in Examples 3 and 4 in columns 11-14. In column 13, line 1, through column 14, line 51, a hybridization assay is described wherein target DNA is immobilized onto a membrane, hybridized with a probe which is labeled for detection. The detection of the hybridized probe is performed via the visualization described in example 3 in column 12, lines 15-44, wherein the enzyme, alkaline phosphatase, is reacted via attachment to the probe which is immobilized on the membrane in a conjugate which then is visualized via color reaction. It is noted that the instant claims do not limit what type of reaction which the enzyme performs with the immobilized substrate on the membrane.

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to perform the electroblotting of Kreisher to immobilize a substrate nucleic acid onto a membrane which is then reacted via binding reactions with an enzyme as in Ramachandran et al. to result in the practice of the instant invention to obtain the benefits of color detection via the labels as in Ramachandran et al.

No claim is allowed.


Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

December 12, 2003

  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER